

PTO/55/03A (02-03)

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Substitute for form 1449, PTO 10/2002

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/669,250
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

Sheet 1 of 17

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (U.S. Pat.)			
[Signature]	1	US- 4,021,472 A	05/1977	Fujii et al.	
	2	US- 4,051,842 A	10/1977	Hazel et al.	
	3	US- 4,140,122 A	02/1979	Kuhl et al.	
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	16	US- 4,829,052 A	05/1989	Glover et al.	
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	18	US- 4,843,094 A	06/1989	Imaki et al.	
[Signature]	19	US- 4,889,723 A	12/1989	Kim et al.	

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁵
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
[Signature]	20	WO 94/07525	04/1994			
	21	WO 95/28422	10/1995			
	22	WO 95/34538	12/1995			
	23	WO 96/12021	04/1996			
	24	WO 96/14067	05/1996			
[Signature]	25	WO 97/03679	02/1997			

Examiner
Signature [Signature]Date
Considered

1-3-06

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Sheet 2 of 17

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W	26	US- 4,931,279 A	06/1990	Bawa et al.	
	27	US- 4,963,654 A	10/1990	Katunuma	
	28	US- 5,004,612 A	04/1991	Kim et al.	
	29	US- 5,077,428 A	12/1991	Imaki et al.	
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	39	US- 5,416,191	05/1995	Cheronis et al.	
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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
W	45	WO 97/09346	03/1997			
	46	WO 97/09347	03/1997			
	47	WO 97/10222	03/1997			
	48	WO 97/10231	03/1997			
	49	WO 97/21690	06/1997			
	50	WO 97/24339	07/1997			

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Attorney Docket Number	330310.00103

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		Number-Kind Code ² (if known)			
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		Country Code ² Number ³ Kind Code ⁵ (if known)				
W	70	WO 97/31937	09/1997			
	71	WO 97/33996	09/1997			
	72	WO 97/37969	10/1997			
	73	WO 97/45402	12/1997			
	74	WO 97/48706	12/1997			
W	75	WO 97/49679	12/1997			

Examiner Signature	<i>W. Collette</i>	Date Considered	1-3-06
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Sheet 4 of 17

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Application Number	10/669,250
Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

U. S. PATENT DOCUMENTS

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		Number-Kind Code ² (if known)			
100	76	US- 5,663,416 A	09/1997	Kirschenheuter et al	
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100	95	WO 98/06417	02/1998			
	96	WO 98/09206	03/1998			
	97	WO 98/20034	05/1998			
	98	WO 98/21186	05/1998			
	99	WO 98/22098	05/1998			
	100	WO 98/22619	05/1998			

Examiner
Signature

Leland Shapiro

Date
Considered

1-3-06

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	101	US- 5,861,380 A	01/1999	Gyorkos et al.	
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	104	US- 5,874,424 A	02/1999	Batchelor et al.	
	105	US- 5,874,585 A	02/1999	Gyorkos et al.	
	106	US- 5,891,852 A	04/1999	Gyorkos et al.	
	107	US- 5,914,342 A	06/1999	Maurer et al.	
	108	US- 6,127,356 A	10/2000	Crapo et al.	
	109	US- 6,140,116 A	10/2000	Dinsmore et al.	
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	226	US- 5,376,655 A	12/1994	Imaki et al.	
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	112	WO 98/23565	06/1998		
	113	WO 98/24806	06/1998		
	114	WO 98/46597	10/1998		
	115	WO 98/49190	11/1998		
	116	WO 98/50342	11/1998		
	117	WO 98/50420	11/1998		

Examiner Signature	<i>W. C. Lee</i>	Date Considered	1-3-06
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Sheet	6	of	17
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10	118	WO 98/56821	12/1998			
	119	WO 97/41231	08/1999			
	120	WO 99/43308	09/1999			
10	121	WO 00/52034	09/2000			

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Sheet	7	of	17

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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
W	122	Aoki H, Akaiki T, Abe K, Kuroda M, Arai S, Okamura R, Negi A, Maeda H. Antiviral effect of oryzacystatin, a proteinase inhibitor in rice, against herpes simplex virus 1 in vitro and in vivo. Antimicrob Agents Chemother Apr. 1995; 39(4):846-9.	
f	123	Auerswald et al., "Recombinant leech-derived trypsin inhibitor: construction, production, protein chemical characterization and inhibition of HIV-1 replication", Biol Chem Hoppe Seyler, 375(10):695-703 (1994).	
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	128	Cox et al., "Synergistic combinations and peptides in the inhibition of human immunodeficiency virus", Adv Enzyme Regul, 31:85-97 (1991).	
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Examiner Signature		Date Considered	1-3-06
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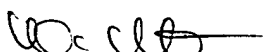
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known			
		Application Number	10/669,250		
		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
		Art Unit	1645		
		Examiner Name	Not Yet Assigned		
Sheet	8	of	17	Attorney Docket Number	330310.00103

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
lc	132	Flaitz CM, Hicks MJ. "Molecular piracy: the viral link to carcinogenesis." Oral Oncol Nov. 1998;34(6):448-53.	
	133	Griffin, William C., "Calculation of HLB Values of Non-Ionic Sufactants", [H. L. B.--The Hydrophilic-Lipophilic Balance], J. Soc. Cos. Met. Chem., vol. 5, p. 249 (1954).	
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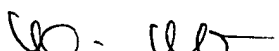
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		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
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le	142	Meylan et al., "HIV infectivity is not augmented by treatment with trypsin, Factor Xa or human mast-cell tryptase", AIDS, 6(1):128-30 (1992).	
f	143	Miranda et al., "Isolation of the human PC6 gene encoding the putative host protease for HIV-1 gp160 processing in CD4+ T lymphocytes", Proc Natl Acad Sci U S A, 93(15):7695-7700 (1996).	
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Filing Date	September 25, 2003
First Named Inventor	Leland SHAPIRO
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	330310.00103

Sheet 10 of 17

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le	152	Cilberto et al., 1985, Cell, 41:531-540.	
	153	Dery O. and Bunnett, N.W. Biochem Soc Trans 1999, 27, 246-254.	
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		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
		Art Unit	1645		
		Examiner Name	Not Yet Assigned		
Sheet	11	of	17	Attorney Docket Number	330310.00103

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le	162	Nathan, C. in FASEB J. 1992, 6, 3501.	
	163	Rehman, A. et al. in Br J Pharmacol, 1997, 122, 1702.	
	164	Pryor, W. A. et al., in Chem Biol Interact 1985, 54, 171.	
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le	172	Schini et al. in Circ Res 1994, 74, 24.	
f	173	Meki, A. R. et al. in Toxicol 1998, 36, 18519.	
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	180	Merrifield, R.B., "Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide", 1963, J. Am. Chem. Soc., (85):2149.	
le	181	Animal Cell Culture, R.I. Freshney, ed. 1986, IRL Press, Oxford.	

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lc	182	Scharpe et al., "Protease and their inhibitors: today and tomorrow", 1991, Biochimie, 73(1):121-126.	
	183	Kido et al., "A novel membrane-bound serine esterase in human T4+ lymphocytes immunologically reactive with antibody inhibiting syncytia induced by HIV-1. Purification and characterization", J Biol Chem., 1990, 265(35):21979-85.	
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	185	Auerswald et al., "K15R M52E) aprotinin is a weak Kunitz-type inhibitor of HIV-1 replication in H9 cells" Biomed Biochim Acta, 1991, 50(4-6):697-700.	
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ll	191	Anderson et al., "Inhibition of HIV-1 gp160-dependent membrane fusion by a furin-directed alpha 1-antitrypsin variant", 1993, J Biol Chem, 268(33):24887-91.	

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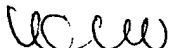
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le	192	Decroly, et al., "Identification of the paired basic convertases implicated in HIV gp160 processing based on in vitro assays and expression in CD4(+) cell lines", 1996, J Biol Chem, 271(48):30442-50.	
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16	202	Premack, B.A. et al., "Chemokine Receptors: Gateways to Inflammation and Infection", 1996, Nature Medicine 2:1174-1178.	
	203	Zhirnov O.P. et al., "Antiviral activity of proteinase inhibitors in cultured cells infected with alpha-viruses", Mol Gen Mikrobiol Virusol, 1985, (12):30-6.	
	204	Chesnokova N.B. et al., "Antiproteases in herpetic keratitis", Metab Pediatr Syst Ophthalmol, 1986;9(1):593-6.	
	205	Adelman S.F. et al., "Protease inhibitors suppress fibrinolytic activity of herpesvirus-transformed cells", J Gen Virol, 1982, 60(Pt 1):15-24.	
	206	Chesnokova N.B. et al., "Main proteolytic inhibitors in ocular herpes", Vopr Med Khim, 1981, 27(5):663-5.	
	207	Sharpstone D. et al., "Faecal alpha 1 antitrypsin as a marker of gastrointestinal disease in HIV antibody positive individuals", Gut, 1996, 38(2):206-10.	
	208	Patel et al., "The Role of Protease Drug During Apoptosis", 1996, FASEB J, 10(5):587-597.	
	209	Estaquier J., "Fas-mediated apoptosis of CD4+ and CD8+ T cells from human immunodeficiency virus-infected persons: differential in vitro preventive effect of cytokines and protease antagonists", 1996, Blood, 15;87(12):4959-66.	
	210	Shimizu, T. et al., "DNA Fragmentation induced by Protease Activation in P53-null Human Leukemia HL60 Cells Undergoing Apoptosis Following Treatment with the Topoisomerase I Inhibitor Camptothecin: Cell-Free System Studies", 1996, Exp Cell Res, 1:226(2):292-301.	
W	211	Glynn et al., "Apoptosis induced by HIV Infection in H9 T Cells is Blocked by ICE-Family Protease Inhibition but not by a FAS(CD95) Antagonist", 1996, J. Immunol, 1; 157(7):2754-2758.	

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1-3-06

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/669,250
		Filing Date	September 25, 2003
		First Named Inventor	Leland SHAPIRO
		Art Unit	1645
		Examiner Name	Not Yet Assigned
Sheet 16 of 17	Attorney Docket Number	330310.00103	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
(6)	212	Ooka, T., et al., "Protective effects of human urinary trypsin inhibitor against trypsin-induced relaxation in rat aorta", Crit care Med, 1996, 24(11): 1903-1907.	
	213	Novradovsky, A., et al., "Endothelial Nitric Oxide Synthase as a Potential Susceptibility Gene in the Pathogenesis of Emphysema in alpha1-Antitrypsin Deficiency", 1999, Am J Respir Cell Mol Biol, 1;20(3):441-447.	
	214	Cordiali Fei et al., "Behavior of several 'progression markers' during the HIV-Ab seroconversion period. Comparison with later stages", 1992, J Biol Regul Homeost Agents, 6(2):57-64).	
	215	Lima et al., "Mucosal injury and disruption of intestinal barrier function in HIV-infected individuals with and without diarrhea and cryptosporidiosis in northeast Brazil". 1997, Am J Gastroenterol, 92(10):1861-6.	
	216	Banfi et al., "Tumor-associated trypsin inhibitor in induced and acquired immunodeficiency. Studies on transplanted and HIV-infected patients", 1991, Scand J Clin Lab Invest 51, Suppl, 207:55-8.	
	217	Deam et al., "Alpha 1-antitrypsin phenotypes in homosexual men", 1989, Pathology, 21(2):91-2.	
	218	Pezzilli et al., "Serum pancreatic enzymes in HIV-seropositive patients", Dig Dis Sci, 1992, 37(2):286-8.	
	219	Tang et al., "Inactivation of HIV-1 by trypsin and its use in demonstrating specific virus infection of cells", 1991, J Virol Methods, 33(1-2):39-46.	
	220	Glozman, "Immunologic functions of enzyme therapy of patients with orchiepidymitis", 1990, Antibiot. Khimioter, 35(7):50-52.	
(6)	221	Franzusoff, et al., "Biochemical and genetic definition of the cellular protease required for HIV-1 gp160 processing", 1995, J Biol Chem, 270(7):3154-9).	

Examiner Signature	<i>[Signature]</i>	Date Considered	1-7-06
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		Application Number	10/669,250		
		Filing Date	September 25, 2003		
		First Named Inventor	Leland SHAPIRO		
		Art Unit	1645		
		Examiner Name	Not Yet Assigned		
Sheet	17	of	17	Attorney Docket Number	330310.00103

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W	222	Gu et al., "Furin is important but not essential for the proteolytic maturation of gp160 of HIV-1", FEBS Lett. 1995, 365(1):95-7.	
W	223	Bukrinskaia A.G., "Suppression of rotavirus SA-11 reproduction by protease inhibitors in cell culture", Vopr Virusol, 1987, 32(1):71-4.	

Examiner Signature		Date Considered	1-3-06
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